PATENT

In the UNITED STATES PATENT and TRADEMARK OFFICE

APPLICANT:	Lai, et al.	EXAMINER:	Fubara, Blessing M.
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TITLE:	**ENTERAL FORMULATIONS**		

I certify that this correspondence (along with any paper referred to as being attached or enclosed) is being deposited with the United States Postal Service with sufficient postage as first class mail addressed to the Assistant Commissioner for Patents, Washington, D.C., 20231 on the date shown below.

Wendy Detwiler 3/20/03
Wendy Detwiler Date

Assistant Commissioner for Patents
Washington, D.C. 20231

REMARKS

This amendment is in response to the Office Action mailed September 20, 2002. A request for a three-month extension of time accompanies this response. Claims 1-15 remain active in this application. Claim 15 is allowed in the Office Action. Claim 4 has been canceled. In this amendment, the Applicants have amended claims 1, 3 and 11. Claim 11 has been amended to delete "modified cellulose" from the list of fibers because there is no support in the written description. Claims 1 and 3 have been amended to specify that the stabilizing protein be selected from a group of vegetable proteins. Support for the vegetable stabilizing proteins may be found on page 6, lines 20 through 25.

Claims 1-14 were rejected under 35 U.S.C. 103(a) as being unpatentable over Henningfield et al (US 5,221,668). Henningfield teaches a liquid nutritional product with a protein system comprising lactalbumin hydrolysate (whey protein) and partially hydrolyzed caseinate (casein protein), a lipid system and a source of carbohydrate. Henningfield does not teach the incorporation of vegetable proteins into the protein system. Henningfield stresses the importance of utilizing high-quality proteins and good quality protein based on protein efficiency ratio in the formulation. (Described in Henningfield page 11, last sentence; page 12, last paragraph, second sentence; and page 13, second paragraph.) Consequently, the Henningfield formulation utilizes high quality casein and whey protein. One of ordinary skill in the art would not have readily

substituted vegetable proteins for milk proteins because vegetable proteins do not have the high biological value of milk proteins.

One of the most common biological methods for evaluating the nutritional value of proteins is the protein efficiency ratio (PER). The PER shows how well test animals utilize protein by measuring their weight gain on a controlled diet. The more weight gain per unit of protein intake, the higher the PER of the tested protein. Milk proteins rank higher on the PER scale when compared to vegetable proteins. For example, the PER for: whey protein concentrate is 3.0; lactalbumin is 2.9; milk protein isolate is 2.8; casein is 2.5; rice is 2.2; soy protein isolate is 1.8; and wheat gluten is 1.1. The Henningfield inventors specifically selected two high quality protein sources for their trauma/surgery formulation, lactalbumin protein (PER=2.9) and casein protein (PER=2.5). They do not discuss substituting lesser quality soy protein (PER=1.8). Further information about protein quality and PER may be found in the attached New Zealand Milk Products, Inc. literature titled A Guide to the Benefits of Milk Protein.

Additionally, as described on page 3, lines 8 through 17 of the written description, one of ordinary skill in the art would not replace a casein protein, accepted in the art as an emulsifying protein, for a vegetable protein that does not posses the emulsifying qualities and in fact destabilizes the formulation at levels above 60%. The Applicant's finding that caseinate actually destabilizes the enteral formula by promoting phase separation was entirely unexpected and the remedy is not suggested or taught in Henningfield.

In light of the foregoing, Applicant respectfully requests examination and allowance of the currently pending claims. Applicant request the Examiner to contact Applicant's Representative below, if doing so may expedite disposition of this case.

Respectfully submitted,

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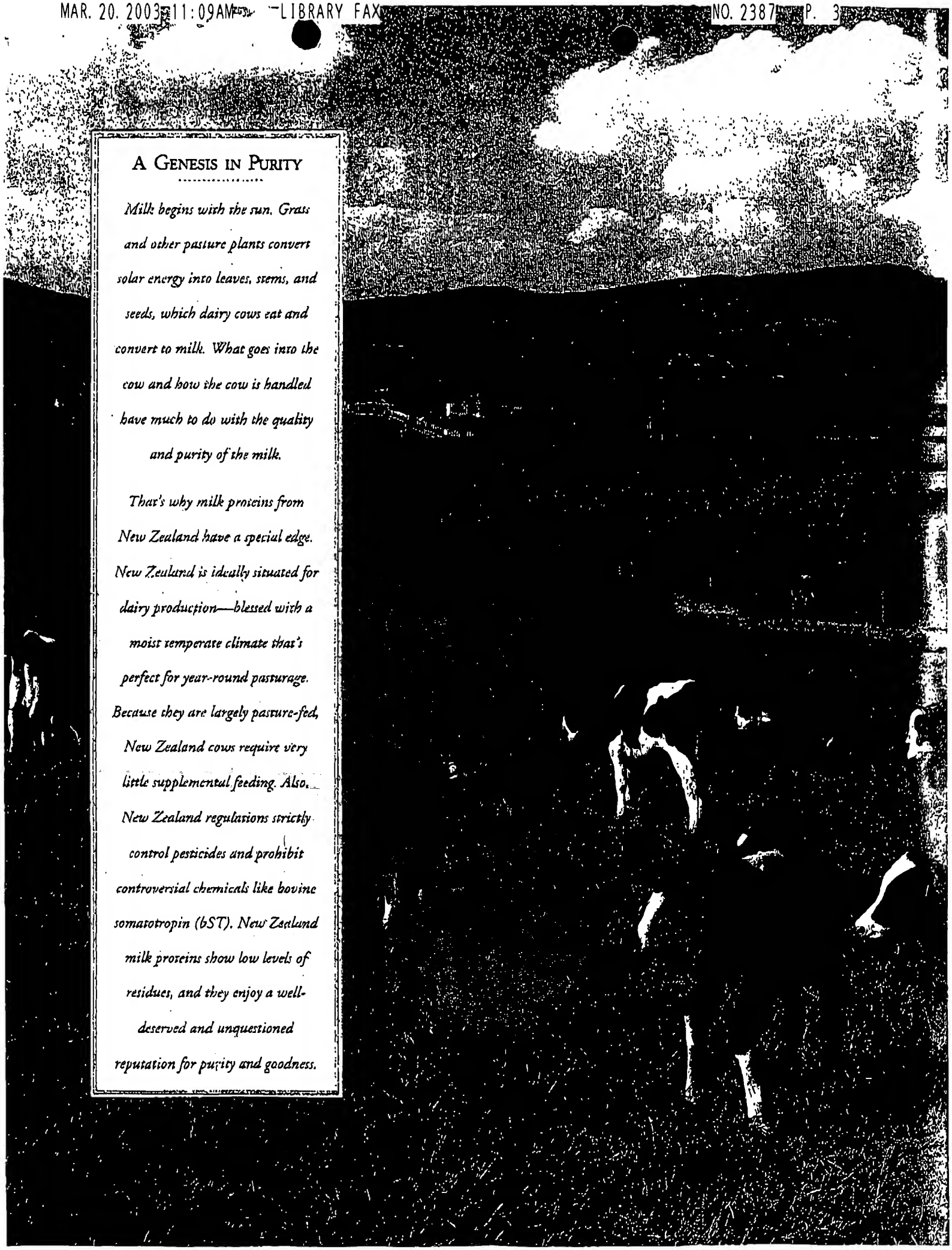
A GUIDE T THE

Benefits of Milk Protein

Milk Protein

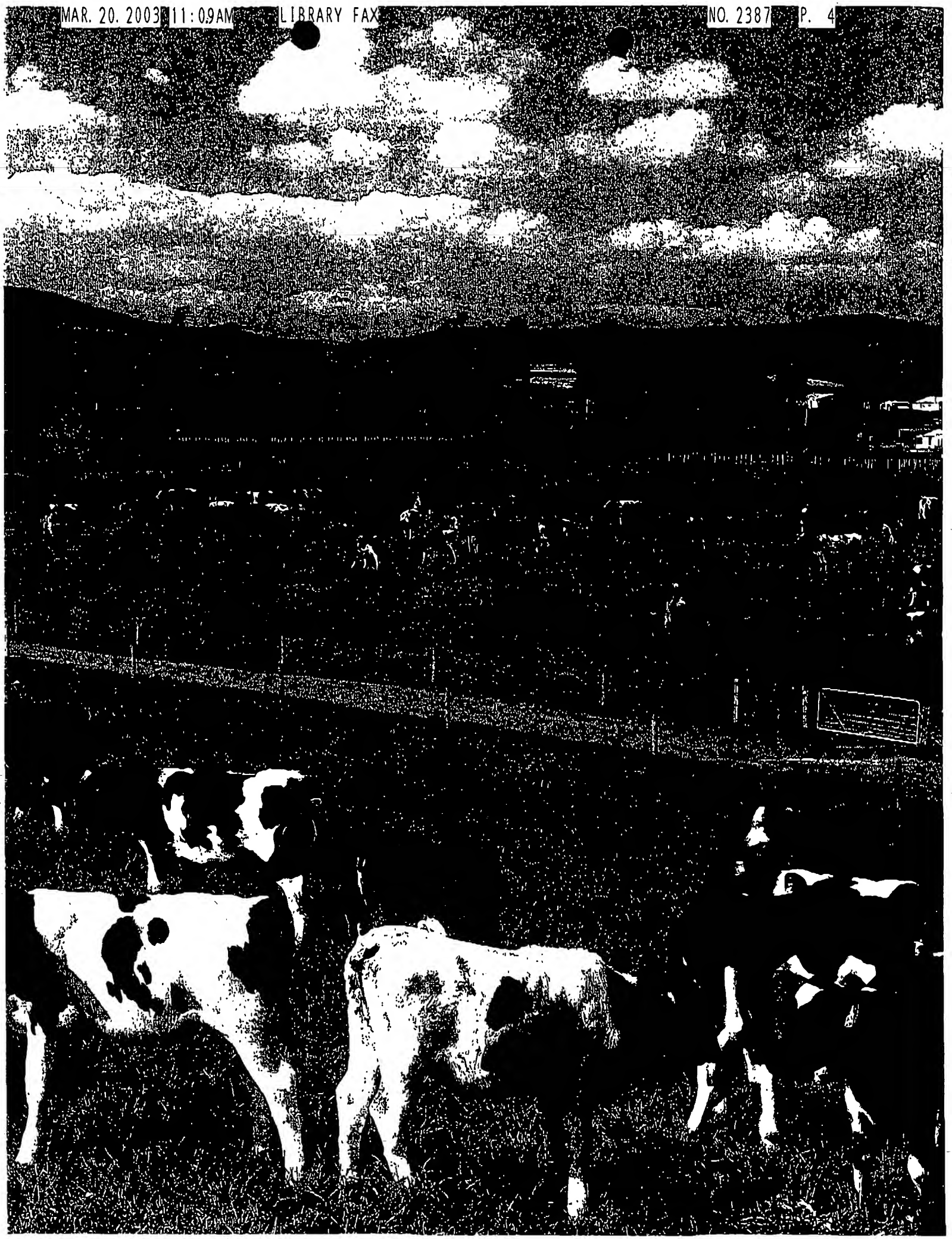
There is no better, more versatile source of protein than milk. Simply, milk protein is the protein of choice.



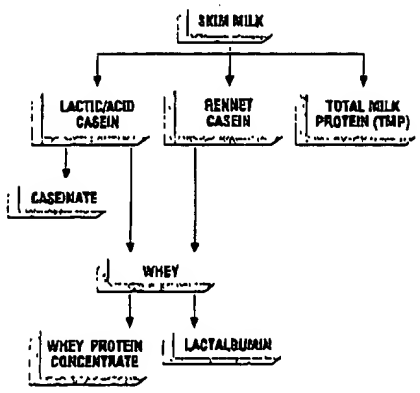
A Genesis in Purity

Milk begins with the sun. Grass and other pasture plants convert solar energy into leaves, stems, and seeds, which dairy cows eat and convert to milk. What goes into the cow and how the cow is handled have much to do with the quality and purity of the milk.

That's why milk proteins from New Zealand have a special edge. New Zealand is ideally situated for dairy production—blessed with a moist temperate climate that's perfect for year-round pasturage. Because they are largely pasture-fed, New Zealand cows require very little supplemental feeding. Also, New Zealand regulations strictly control pesticides and prohibit controversial chemicals like bovine somatotropin (bST). New Zealand milk proteins show low levels of residues, and they enjoy a well-deserved and unquestioned reputation for purity and goodness.



Breakdown f Milk



It's all too easy to take milk for granted, to dismiss it as simply a pleasant beverage for children and adolescents. But milk is much more than something to pour on the morning cereal. It is the source of a wide range of proteins that deliver nutrition and health to today's most promising new food products. Isolated milk proteins are natural, trusted ingredients with superior functionality.

Milk's Many Proteins

One of the reasons why milk is such a good food is that it contains a wide variety of different proteins. Milk proteins are of two basic types: *casein proteins* and *whey proteins*. Casein, the primary protein type, occurs as complexes, or micelles, in fresh milk, while the whey proteins are soluble in the milk's serum phase. There is considerable diversity among these proteins. Additionally, they can be treated in various ways to yield a range of ingredients with diverse functional characteristics from which to choose.

Casein is extracted from milk by isoelectric or enzymatic precipitation. *Acid casein* is manufactured by adding acid to skim milk until the pH drops to 4.6, causing the casein to precipitate from the whey. For *lactic casein*, microbial cultures are added to milk to convert lactose to lactic acid, lowering the pH and precipitating the casein. After it is washed with water, lactic and acid casein can be resolubilized by adding alkali or an alkaline salt to form *caseinate*.

Rennet casein is yet another type of casein. The enzyme rennet, instead of acid, is used to precipitate the casein, yielding a protein with high levels of calcium.

Whey proteins are a more diverse group than the casein proteins. Most are globular, complex molecules cross-linked into defined structures. Heating the whey remaining after casein or cheese manufacture yields an insoluble denatured protein known as *lactalbumin*. Alternatively, whey can be ultrafiltered to remove some of the lactose, yielding *whey protein concentrate (WPC)*. Because processing at high heat is avoided, New Zealand WPCs remain soluble and functional.

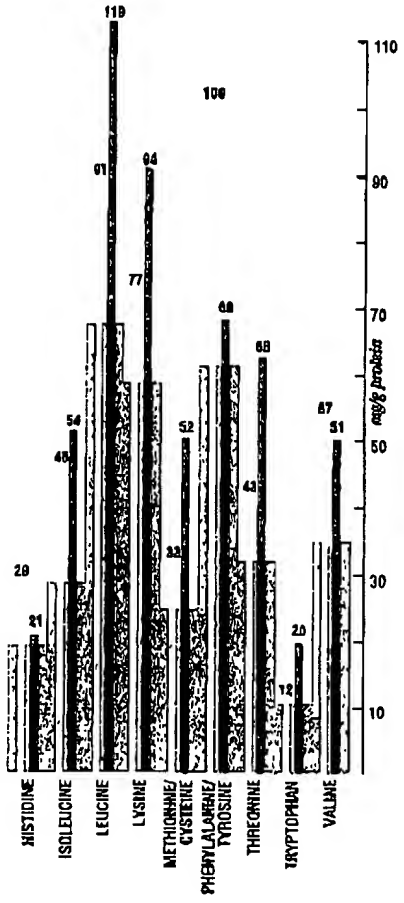
Several years ago, New Zealand Milk Products patented a process for a new type of milk protein precipitate that recovers the whey proteins, as well as the casein, without high heat. This product is called *Total Milk Protein (TMP)*, which food processors typically list as "milk protein isolate" on product labels.

Another group of milk protein products is known as *milk protein hydrolysates*. They are manufactured by enzyme hydrolysis of casein, TMP, lactalbumin, or WPC. Many

Healthy Life Style

As more and more people pursue fitness and health, they are turning to milk protein for the complete, balanced nutrition an active life style requires.

Amino Acid Profile



Suggested Requirement for Preschool Child (FAO/WHO 1989)

Casein/Caseinate

Whey Protein

different hydrolysates are available, depending on the substrate used and the intended function of the end product.

Protein: A Key to Good Health

To maintain good health, humans must consume protein as a source of amino acids. When you eat protein, digestive enzymes break the large, complex protein molecules into small amino acid chains, or peptides, and free amino acids, which are then absorbed from the digestive tract into the bloodstream. The peptides and amino acids are distributed throughout the body for growing and repairing muscle and connective tissue, synthesizing enzymes and certain hormones, supplying metabolic energy, providing the principal cellular buffer system, and playing other critical physiological roles.

Proteins occur in all sorts of food, both animal and vegetable, but not all proteins are created nutritionally equal. In large measure, this difference among proteins has to do with varying levels of the *essential amino acids*—amino acids that cannot be synthesized within the human body and must be supplied by the diet.

Basically, a given protein is only as good as its least abundant amino acid—which is called the *limiting amino acid*. Take wheat protein as an example. Lysine is the limiting amino acid, at only 26% of the level recommended in the FAO/WHO (1989) amino acid pattern. To meet the lysine requirement, a diet based on wheat as the protein source must contain a much larger amount of that food than does a diet based on a superior protein source, like milk.

A limiting amino acid can also be overcome by combining proteins. For example, combining milk protein—which is rich in lysine—with wheat protein—which is deficient in lysine—boosts the overall protein value of products made with flour.

Picking a Protein: Which Is Best?

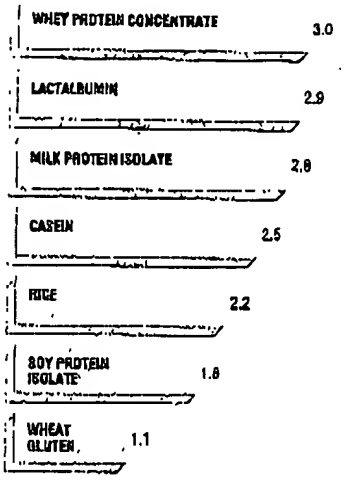
There are two basic ways to evaluate the nutritional value of proteins: analytical and biological. Each of the evaluative methods has specific benefits and limitations, but when the results of all measures are put together, a clear picture emerges.

Chemical score is an example of an analytical method. The chemical score

expresses the amount of the first limiting amino acid as a percentage of the recommended level. The higher the score, the better the protein. Milk proteins have much higher scores than do vegetable proteins like wheat gluten and soy protein isolate.

The drawback to analytical methods is that they do not account for what happens to the protein inside the body. Biological methods, on the other hand, measure protein performance in vivo. One of the most commonly used biological methods is the *protein efficiency ratio (PER)*. PER shows how well test animals utilize protein by measuring their weight gain on a controlled diet. The more weight the animals gain per unit of protein intake, the higher the PER of the tested protein. As with the chemical score, milk proteins rank high on the PER scale, much higher than do vegetable proteins.

Protein Efficiency Ratio



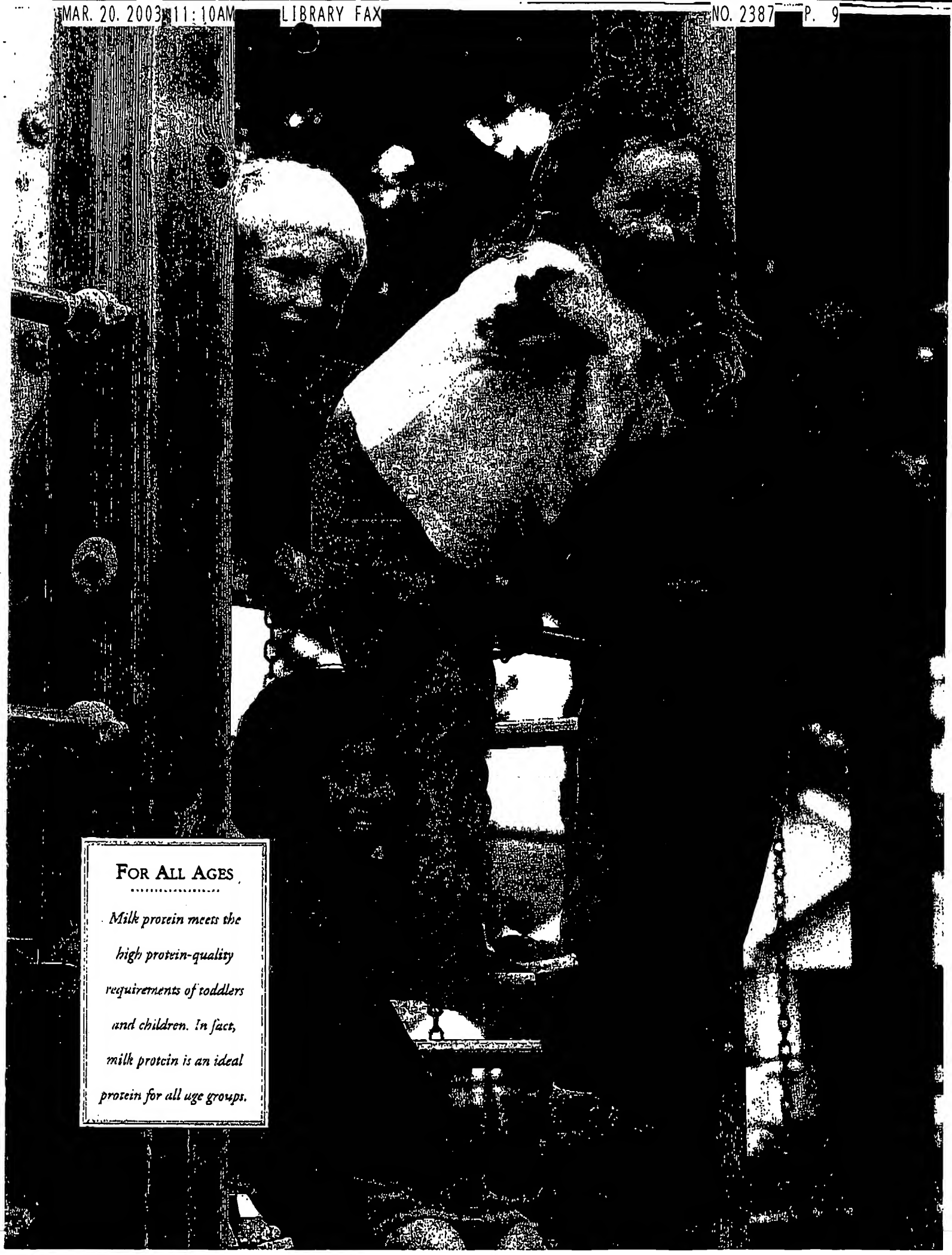
There are limitations with PER measurements, however. The tests are performed in rats, not humans, and results may not be comparable. Also, PER scores are nonlinear; that is, the protein value of a given quantity of a food with a PER of 1.3 is not simply half as good as the same quantity of another food with a PER of 2.6. Likewise, PERs are nonadditive; that is, they cannot be used to determine the nutritive value of a mixture of different proteins.

Still, the bottom line remains the same. By both analytical and biological methods, milk protein ranks right at the top as an excellent source of the complete, balanced protein humans need. Simply put, there is no more versatile protein than milk protein.

How Much Protein Is Enough Protein?

The United States is the scene of considerable governmental and scientific debate over the best way to state the nutritive content and quality of food products. Various methods of calculating protein quality evaluations for nutritional labeling declarations are being considered.

Under current U.S. regulations, the amount of protein a person over four years old should consume per day depends upon the PER of the protein source. If the protein source has a PER of 2.5 or more—as milk protein does—the diet should include 45 grams of that source. If the PER is less than 2.5, the diet should include 65 grams. The requirements for pregnant and lactating women are higher.



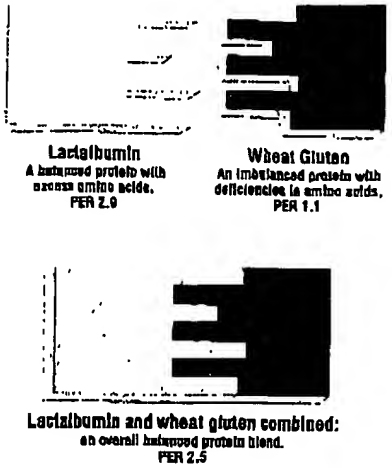
For All Ages

Milk protein meets the high protein-quality requirements of toddlers and children. In fact, milk protein is an ideal protein for all age groups.

An alternative method has been endorsed by the United Nations' Food and Agriculture Organization (FAO) and World Health Organization (WHO), which are particularly concerned about nutrition in Third World countries. This method, called the *protein digestibility–corrected amino acid score (PD-CAA)*, uses amino acid scores adjusted by data on protein digestibility. Ideally, the digestibility data are taken from humans; in fact, though, rats have been used for routine assays. Supporters of PD-CAA argue that this method more accurately reflects the nutritional requirements of humans while incorporating allowances for the biological value of the protein in a simple, accessible calculation. However, PD-CAA fails to account for the varying digestibilities of specific amino acids, and it may overestimate the ability of vegetable proteins to meet human requirements, particularly for the sulphur amino acids.

PD-CAA scores for milk protein are uniformly high, indicating that caseinate, whey proteins, and TMPs are excellent complete protein sources for both children and adults. Indeed, no matter which method of evaluating protein quality is chosen, milk protein ranks highly for people of all ages.

Complementary Protein Blends



Blend	Ratio	PER
Lactalbumin - Wheat Protein	50:50	2.5
Casein - Soy Protein Isolate	75:25	2.5
Milk Protein Isolate - Wheat Protein	50:50	2.5

Working Alone or Lending a Hand

Milk protein is a rich source of essential amino acids all by itself. In addition, it can be used as a complementary protein. That is, milk protein can be used to boost the nutritional quality of other proteins, particularly vegetable isolates that are limiting in one or more of the essential amino acids.

Since milk protein is often rich in the very amino acids that are limiting in vegetable proteins, combining the two boosts overall protein quality. A small amount of milk protein added to a food product formulation can markedly increase overall protein value.

The Special Protein for Special Diets

Everybody needs protein, but some people need it more than others. In different life styles and at different life stages, we humans have special protein requirements.

The young. Childhood is one such stage. Because children are growing so fast, and because healthy development in the child is critical to health and happi-

ness in later life, meeting the protein requirement is crucially important. According to the FAO/WHO recommendation, for example, infants need to consume an average of 460 milligrams of the essential amino acids for each gram of crude protein, while adults require only 127 milligrams. Products formulated for young consumers—and products formulated for all age groups, children included—need to take children's high protein-quality requirements into account. Since children eat small volumes of food, milk protein ingredients, with their rich essential amino acid content, help ensure that the daily protein requirement is satisfied.

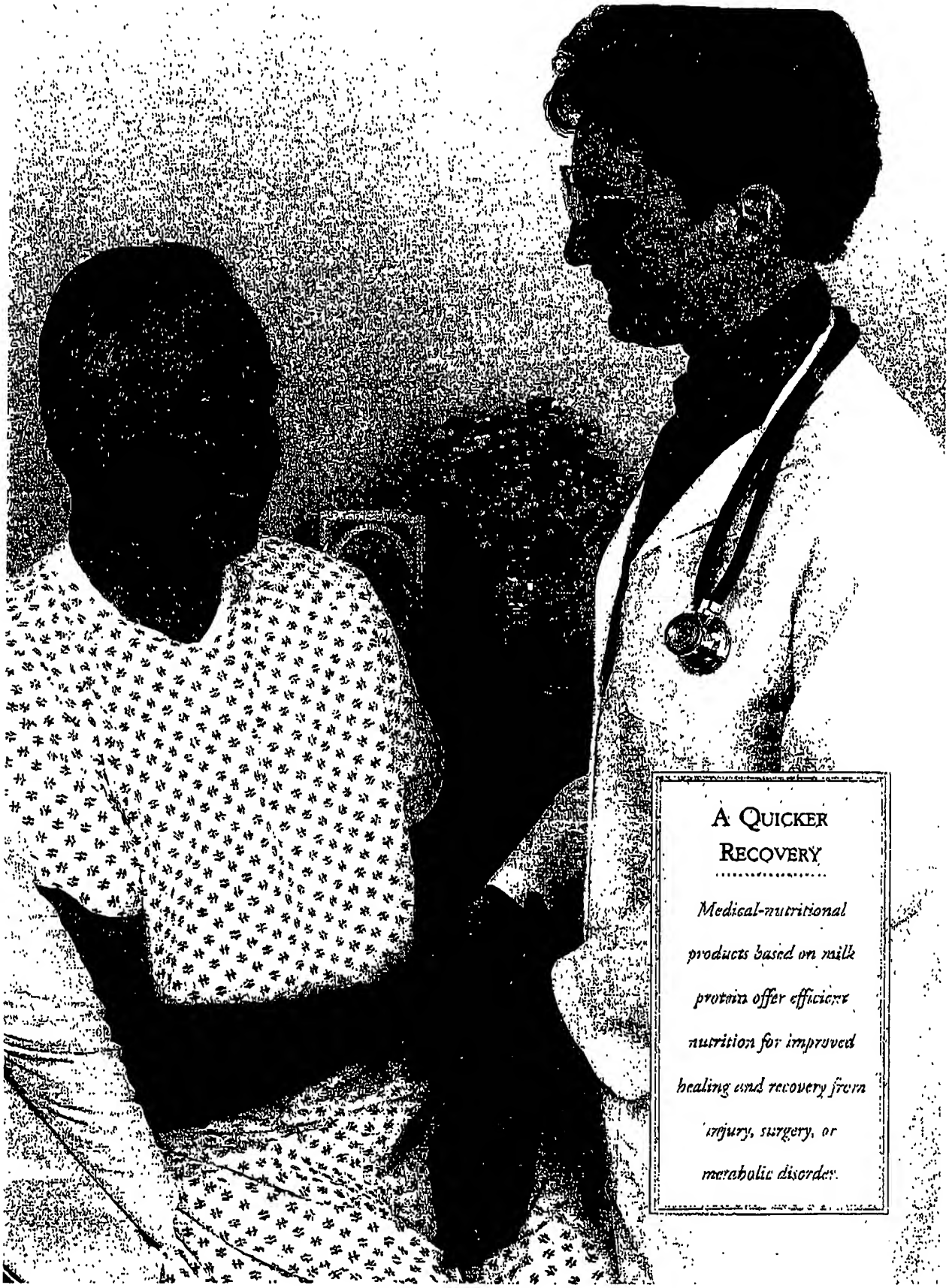
Senior adults. While the amount of protein required does not increase over age 65, seniors need fewer calories and tend to eat less than younger adults. As a result, they often consume too little protein. One clinical study found that a startling 50% of hospitalized and convalescent elderly were protein-malnourished.

One solution is enteral products, medical-nutritional supplements that deliver the right balance of the right nutrients. Including milk protein in the formulation ensures that the amino acid balance of an enteral product is precisely what senior adults need.

The ill and the injured. Medical-nutritional products are also finding increasing use for patients who have undergone trauma, from surgery or accident, or who suffer from diseases causing metabolic imbalance. Practically all medical-nutritional formulas are based on milk protein, which is readily absorbed, has a bland taste, and can be engineered to meet the specific needs of particular medical conditions.

Athletes and weekend warriors. Bodybuilders, power lifters, shotput and discus throwers, football players, swimmers, cyclists, runners, speed walkers, and other athletes who require strength and power typically supplement their diets with protein. Milk protein, either alone or as a complement to vegetable proteins, is an excellent supplement for athletes. Milk protein contains a large proportion of branched-chain amino acids, which, according to mostly anecdotal evidence, may augment both bodybuilding and endurance. Other studies indicate that whey proteins enhance the immune system, which may be impaired by severe training regimens.

What goes for fulltime athletes should also apply to healthy adults who pursue sports training as part of their health and fitness routine. Products made with milk protein are ideal because of their overall nutritional benefit.


A QUICKER RECOVERY
Medical-nutritional products based on milk protein offer efficient nutrition for improved healing and recovery from injury, surgery, or metabolic disorder.

Milk proteins have a functional as well as a nutritional role in the physiological well-being of mammals, including humans.

There's More to Milk Protein Than Just Protein

In recent years, researchers have uncovered ways that milk and milk proteins actually improve the digestion and absorption of nutrients, both from milk and from other sources. These nutrients, which belong to that novel class of ingredients known as physiologically functional foods, represent the new frontier in our understanding of milk's nutritional role.

Milk-derived bioactive peptides aid in immune modulation, digestion, pain relief, and mineral absorption. *Casein phosphopeptide* (CPP), for example, may aid in the preferential absorption of calcium and iron from the small intestine. Already CPP is being added to calcium-fortified soft drinks, mineral tablets, and other products in Japan to boost their nutritive efficiency. More applications are in development. In addition, ongoing research is showing that certain other peptides arising naturally from the digestion of milk benefit human health and contribute to well-being.

Lactoferrin, a bioactive milk protein that is particularly abundant in colostrum, is both an excellent iron transporter and a natural antibacterial agent. Lactoferrin may prove useful as a bacteriostat, particularly against dental caries. Similarly, *lactoperoxidase* functions as either a bacteriostat or a bacteriocide depending on environmental conditions.

And that's just the beginning. Every day the list of milk constituents offering unexpected nutritional benefits—and commercial potential as physiologically functional foods—is growing.

Cutting Fat

Milk protein has long proved its worth as a functional fat-replacer in a number of reduced-fat applications, including frozen yogurt and bakery products. Current research is showing how successful milk protein can be in many other applications, including beverages, frozen desserts, dressings, and low-fat cheeses and meats. Milk protein helps restore the mouthfeel and texture lost when fat is removed, while at the same time increasing the protein value of the final product.

Doing Yourself, and Your Customers, a Favor

Milk protein is the ingredient you need to design the next generation of food product successes. Because its functionality can be engineered with remarkable exactness, milk protein offers a way to create products with the mouthfeel, texture, and nutrition consumers want. Milk protein has taste advantages, too; the clean bland flavor doesn't get in the way, unlike the cereal notes left by vegetable proteins. And milk protein allows the kind of clean labeling that attracts health-conscious shoppers.

There's no doubt about it. Milk protein is the protein of choice.

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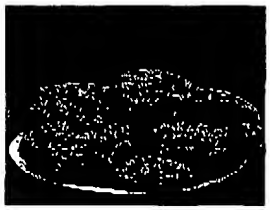
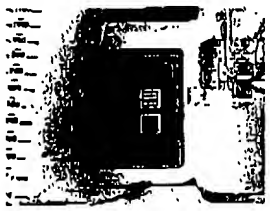
APPLICATIONS

	Application	Required Characteristics	Suggested Products	Product Type
Aerated Products	Frozen Yogurt	Aeration, creamy mouthfeel, acid and structural stability	AlWhip	Modified Milk Protein
	Mousse	Aeration, body & structural stability	AlWhip	Modified Milk Protein
	Nougats	Aeration, foam stability, low sensitivity to hot syrup & resistance to syneresis	AlWhip	Modified Milk Protein
	Whipped Toppings	Emulsification, aeration & structural/ freeze thaw stability	AlWhip	Modified Milk Protein
Restructured Products	Meat	Adhesion, water/fat binding & gel formation similar to myosin	ALACEN	Whey Protein Concentrate
	Non-Specific Loaves & Sausages	Emulsification, water binding	ALANATE	Sodium Caseinate or Calcium Caseinate
			TMP	Total Milk Protein
	Poultry	Adhesion, emulsification water binding	TMP ALANATE	Total Milk Protein Hydrolyzed Sodium Caseinate
Desserts & Confectionery Products	Fortified Confectionery Coatings	Low water absorption capacity	ALANATE	Calcium Caseinate
	Frozen Desserts	Emulsification, texture & structural stability	TMP	Milk Protein Isolate
	Ice Cream/Ice Milk	Viscosity, emulsification & body	ALANATE	Calcium Sodium Caseinate
	Puddings	Thickening, emulsification & structural stability	TMP	Milk Protein Isolate
Dairy Products & Analogs	Coffee Whiteners	Emulsification, whitening & acid stability	ALANATE	Sodium Caseinate
	Imitation Cheese	Emulsification, texture and bland flavor	ALAREN	Rennet Casein
	Low Fat Spreads	Emulsification, viscosity, mouthfeel & flavor	ALANATE	Sodium Caseinate
	Sour Cream Analog	Smooth texture, body, opacity, emulsification & acid stability	ALANATE	Calcium Sodium Caseinate
	Whipped Toppings	Smooth texture, body, opacity, emulsification & acid stability	ALANATE	Sodium Caseinate
Convenience Foods	Canned Cream Soups	Emulsification, water/fat binding, retort stability & low thermophiles	ALANATE	Sodium Caseinate
	Egg Substitutes	Heat-set formation, low cholesterol, opacity and bland flavor	ALACEN	Whey Protein Concentrate
	Salad Dressing and Imitation Mayonnaise	Emulsification, thickening & acid stability Emulsification, thickening, acid stability, opacity & low cholesterol	ALACEN ALANATE	Whey Protein Concentrate Calcium Sodium Caseinate

APPLI ATI NS

Application	Required Characteristics	Suggested Products	Product Type
Bakery Products			
Bakery Blends	Non-fat dairy milk replacers	ALACO	All Dairy Blend
Bakery Glazes	Heat-set film formation & high sheen	ALACO Bakery Glaze	Whey Protein Concentrate & Sodium Caseinate
Batters & Breadings	Increase viscosity, strengthen structure, reduce moisture loss	SAVORLAC or ALACEN	Whey Sodium Caseinate Whey Protein Concentrate
Fortification	Nutritionally complements cereal grains, water absorption, amino acid profile	SAVORLAC	Whey Calcium Sodium Caseinate
		or ALATAL	Lactalbumin
Pasta	Retort & structural stability, nutritional fortification	TMP	Milk Protein Isolate
Health & Nutrition			
Acid Beverages	Acid/heat stability & superior nutritional quality (PER 3.2)	ALACEN	Whey Protein Concentrate
Calcium Fortified Foods	High calcium content, bland flavor, milk-derived calcium source	ALAMIN	Milk Calcium Minerals
Low Sodium Products	Opacity, solubility & low viscosity	ALANATE	Magnesium Caseinate or Potassium Caseinate
	Emulsification, solubility & whippability		
	Dispersibility, opacity, low viscosity & PER (2.8)	TMP	Milk Protein Isolate
Nutritional Beverages	Low viscosity in high-protein solutions, suspension stability & smooth mouthfeel	ALANATE	Calcium Sodium Caseinate
	Dispersibility, suspension stability, opacity & low sodium	ALANATE	Calcium Caseinate
	PER (2.8), low viscosity, dispersibility & opacity	TMP	Milk Protein Isolate
Nutrition Bars -			
Wafers	Controlled aeration & low water absorption capacity	ALANATE	Calcium Sodium Caseinate
Soft Core	Specific water absorption, fat binding & high sheen	ALACEN	Whey Protein Concentrate
Medical Products			
Enteral -			
Standard Retort or UHT Processed	Emulsification, low thermophiles, excellent heat stability & bland flavor	ALANATE	Sodium Caseinate or Calcium Caseinate
	Excellent nutritional quality (PER 2.8), emulsification, excellent heat stability and bland flavor	TMP	Milk Protein Isolate
Lactose Intolerance	Low lactose content	ALANATE	Caseinate
		or TMP	Milk Protein Isolate
		or MPH	Milk Protein Hydrolysate
Trauma	High in di- & tri peptides & supplemented with branched chain amino acids (BCAA content 45%)	MPH	Milk Protein Hydrolysate with Leucine, Isoleucine & Valine
Infant Formula -			
Reduced Allergenicity	Allergenicity reduced by enzyme hydrolysis, excellent nutritional quality, good solubility, low lactose & relatively bland flavor	MPH	Milk Protein Hydrolysate





WORLDWIDE NETWORK

NEW ZEALAND DAIRY BOARD
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New Zealand Milk Products (UK) Ltd.
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Middle East
New Zealand Milk Products (Middle East)
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Commonwealth of Independent States
Sovenz/CIS
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New Zealand Milk Products (North America), Inc.
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The Caribbean, Latin and Central America
New Zealand Milk Products (Florida) Inc.
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New Zealand Milk Products (Japan)
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Southeast Asia
New Zealand Milk Products (SEA) PTE Ltd.
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Australia
Milk Products Holdings (Australia) PTY Ltd.
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